REMARKS

Claims 1 - 4 and 6 are pending in the application. Applicants have amended several of the claims without introducing new matter. Claim 12 has been added and contains selected members of the Markush group of Claim 6. Claim 13 has also been added. It is similar to amended Claim 1 except that it is directed to a method for diagnosing the presence of a pruritic disease. Dependent Claim 2 has been canceled. Accordingly, Claims 1, 3, 4, 6 and 12 – 13 remain pending.

Formal Matters

Applicants note with appreciation the acceptance of the election under the restriction requirement and that Claims 5 and 7 - 11 have been canceled. Applicants specifically reserve the right to pursue the subject matter of the canceled claims in one or more continuing applications.

Specification

Applicants note with appreciation that the objection to the title and to the specification set forth in the previous Office Action have been withdrawn.

Claim Objections

Claim 6 has been amended in light of the Examiner's helpful comments to correct the typographical error.

Claim Rejection 35 U.S.C. §112, first paragraph

Claims 1 - 4 and 6 have been amended to clarify that the examination is performed to diagnose opioid-based pruritis, which allows for appropriate treatment methods. With this clarification, the specification is clearly enabling for diagnosing opioid-based pruritis, regardless of any underlying or resulting condition or disease.

While we agree that opioids can be present for a variety of reasons, Applicants have found that where the ratio of either δ- or μ-opioid peptides to κ-opioid peptides is greater than that found in healthy patients, the result is pruritis. Opioid-based pruritis can be treated, by administering κ-opioid agonistic, among other treatments. Thus, the ratio can be tested and adjusted for any of the pruritic conditions/diseases that are accompanied by an increase in the calculated ratio.

Applicants respectfully submit that, as amended, those claims call for diagnosing opioid-based pruritis and not for diagnosing the underlying condition or disease. Thus, the specification need not teach "the artisan how to identify and differentiate the specific pruritic diseases" as suggested in the Office Action. Accordingly, Applicants respectfully submit that those claims have been amended such that they are fully supported and enabled by the specification.

Applicants also respectfully submit that the claims as amended have been rewritten to emphasize the fact that the method diagnoses opioid-based pruritis regardless of the underlying disease. Accordingly, there is no genus/species in question. Claim 6 sets forth various conditions which may lead to diagnoses and treatment of opioid-based pruritis. Applicants respectfully submit that the claims as amended satisfy all requirements of 35 U.S.C. §112, first paragraph.

We further enclose herewith a Declaration of Mr. Kenji Takamori, whose experience in this field clearly renders him as at least one of ordinary skill in the art. Mr. Takamori has conducted a series of experiments based on the disclosure set forth in the Applicants' specification. Mr. Takamori has specifically conducted experiments wherein he diagnosed and then treated pruritis, which accompanies atopic dermatitis, which is one of the specific pruritic diseases described in the Applicants' specification.

Reference to Mr. Takamori's Declaration demonstrates that, merely by following the steps set forth in Example 2 in the Applicants' specification, one of ordinary skill in the art can practice this invention over a variety of pruritic diseases, far beyond the Example in the specification with respect to pruritis for a patient undergoing hemodialysis. Accordingly, we respectfully submit that Mr. Takamori's Declaration demonstrates that one of ordinary skill in the art can readily practice the invention, with virtually no experimentation at all, over a variety of pruritic diseases in a manner that is fully enabled by the Applicants' disclosure. In other words, Mr. Takamori simply followed the directions set forth in the Applicants' specification and readily diagnosed and subsequently treated pruritis accompanying atopic dermatitis. These same concepts can readily be extended to other types o pruritic diseases such as those described in the Applicants' specification.

As a consequence of the ease with which Mr. Takamori practiced the invention in accordance with a pruritic disease not specifically exemplified (albeit described) in the Applicants' specification, we respectfully submit that such practicing of the invention factually demonstrates enablement of the Applicants' original disclosure. We, therefore, respectfully submit that, not only are the originally filed claims in accordance with 35 U.S.C. §112, but that new Claim 13 is also in full accordance with §112. Withdrawal of the 35 U.S.C. §112 rejection of Claims 1 – 4 and 6 is accordingly respectfully requested.

Claim Rejections - 35 U.S.C. §112, second paragraph

Applicants note with appreciation the withdrawal of all previous rejections based on 35 U.S.C. §112, second paragraph.

Claim Rejections - 35 U.S.C. §102

Applicants note with appreciation the indication that all previous rejections under 35 U.S.C. §102 have been withdrawn in light of previous amendments. With the withdrawal of these rejections, there are no outstanding prior art rejections.

In light of the amendments and comments above, Applicants respectfully submit that all claims are now in condition for allowance. Early reconsideration and allowance of all pending claims is, therefore, respectfully requested.

Respectfully submitted,

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In the Claims (Clean Copy)

1. (Twice Amended) A method for examining a pruritic disease to diagnose opioid-based pruritis, comprising the steps of:

measuring concentrations of κ-opioid peptides and at least one of δ-opioid peptides, μ-opioid peptides, and nociceptin in blood cells, body fluid, or tissue, and

B1

calculating the ratio of said concentrations of at least one of δ-opioid peptides, μ-opioid peptides, and nociceptin to the concentration of κ-opioid peptides,

comparing said calculated ratio to a corresponding ratio in non-pruritic patients; and

diagnosing opioid-based pruritis where said calculated ratio is greater than said corresponding ratio.

B2

4. (Amended) A method according to claim 1, wherein said μ-opioid peptides to be measured are ß-endorphin and said κ-opioid peptides are dynorphin A.

B3

6. (Twice Amended) A method according to claim 1, wherein said pruritic disease is selected from the group consisting of pruritus with atopic dermatitis, neurodermatitis, contact dermatitis, seborrheic dermatitis, autosensitization dermatitis, caterpillar dermatitis, asteatosis, senile pruritus, insect bite, hyperesthesia optica, urticaria, prurigo, herpes, impetigo, eczema, tinea, lichen, psoriasis, scabies, acne vulgaris, malignant tumor, diabetes, hepatic disease, renal failure, hemodialysis, peritoneal dialysis, or pregnancy.

B4

12. (New) A method according to claim 1, wherein said pruritic disease is selected from the group consisting of atopic dermatitis, renal failure, hemodialysis and peritoneal dialysis.

13. (New) A method for diagnosing presence of a pruritic disease, comprising the steps of:

measuring concentrations of κ-opioid peptides and at least one of δ-opioid peptides, μ-opioid peptides, and nociceptin in blood cells, body fluid, or tissue, and

calculating the ratio of said concentrations of at least one of δ-opioid peptides, μ-opioid peptides, and nociceptin to the concentration of κ-opioid peptides,

B4

comparing said calculated ratio to a corresponding ratio in non-pruritic patients; and

diagnosing the presence of pruritic disease where said calculated ratio is greater than said corresponding ratio.